

REMARKS

1. Claims 1-6, 8-17, 20-21, 24-26, and 28-64 were originally presented for examination. In the outstanding Office Action of December 11, 2007, claims 1-6, 8-17, 20-21, 24-26, and 28-62 were rejected. Claims 63 and 64 were made subject to a restriction requirement and withdrawn by the Examiner from consideration. By the foregoing Amendment submitted on January 24, 2008, claims 1, 24, 29 and 59 were amended. No new matter was added. No new claims were added, and claims 63 and 64 were been cancelled.

2. In this corrected amendment, claim 59 is now correctly identified as “currently amended” in the listing of the claims. No other changes have been made from the amendment filed January 24, 2008.

3. Thus, upon entry of this paper, claims 1-6, 8-17, 20-21, 24-26, and 28-62 will be pending in this application. Of these fifty-six claims, four (4) claims (claims 1, 24, 29 and 59) are independent.

4. In view of the above response to the Office Action mailed December 11, 2007, Applicants respectfully request reconsideration.

5. Based on the above Amendments and following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Art of Record

6. Applicants acknowledge receipt of form PTO-892 listing an additional reference identified by the Examiner.

Priority Claim

7. Applicants note with appreciation the Examiner’s acknowledgement of foreign priority under 35 U.S.C. §119.

Restriction Requirement

8. In the outstanding Office Action, the Examiner required restriction of claims 1-62 as being drawn to invention I and claims 63-64 as being drawn to invention II. By the foregoing Amendments, Applicants have cancelled claims 63-64, without prejudice or disclaimer, making the restriction requirement moot. Applicants respectfully request that the restriction requirement be reconsidered and withdrawn.

Claim Rejections – 35 USC § 103

9. Claims 1-4, 7-9, 10, 11, 14-21, 24-30, 32-36, 39-42, 45-58 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,119,044 to Kuzma (“Kuzma”) in view of U.S. Patent No. 1,146,292 to Wappler (“Wappler”). (*See*, Office Action, pg. 3, ¶ 6; pg. 7, ¶ 22.) Similarly, claims 5, 6, 12, 13, 37, 38, 43, 44, and 59-62 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kuzma alone. (*See*, Office Action, pg. 6, ¶ 19.)

10. In rejecting independent claims 1, 24 and 29, the Examiner asserts that Kuzma substantially teaches all elements of Applicants’ claims 1, 24 and 29 except that “Kuzma fails to teach a conical tapered portion tapering and extending distally from the distal end of the electrode array.” (*See*, Office Action, pg. 5, ¶ 18.) The Examiner relies upon Wappler to teach that which is missing from Kuzma. (*See*, Office Action, pg. 5, ¶ 18.)

11. Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1, 24 and 29 for at least the following reasons. First, the Examiner has failed to provide evidence of a proper motivation supporting the proposed combination of the cited references. Second, even if the references were combined as suggested by the Examiner, the proposed combination would still not contain all the elements of Applicants’ claims 1, 24 and 29.

The Combination of Kuzma with Wappler is prima facie Improper

12. The rejection of claims 1, 24 and 29 are *prima facie* improper because it provides no appropriate basis for combining Kuzma with Wappler. As set forth in the Manual of Patent Examining Procedure (MPEP) at § 706.02(j), “[t]o establish a *prima facie* case of obviousness . . . there must be some suggestion or motivation, *either in the references themselves or in the*

knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings (emphasis added) . . . The teaching or suggestion to make the claimed combination and the reasonable expectation of success ***must both be found in the prior art and not based on applicant's disclosure*** (emphasis added). *In re Vaeck*, 947 F.2d. 488, 20 USPQ2d 1438 (Fed. Cir. 1991).”

13. In the rejections of claims 1, 24 and 29, the Examiner asserts several possible reasons to explain why one of ordinary skill in the art would have been motivated to modify the teachings of Kuzma to include the a tip member having a conical tapered portion of Wappler. Specifically, the Examiner asserts that:

“Wappler teaches that it is known to have a conical tapering at the distal end of an electrode array... for providing the predictable results of preventing foldover of the tip member and also facilitating insertion of the electrode array. ***It would have been obvious*** to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kuzma with a conical tapered portion tapering and extending distally from the distal end of the electrode array, since such a modification was known in the art ***to provide the predictable results of preventing foldover of the tip member*** and also facilitating insertion of the electrode array. (See, Office Action, pg. 5-6, ¶ 18 (emphasis added).)

14. Wappler fails to provide any teaching or suggestion that would motivate one of ordinary skill in the art to make the combination proposed by the Examiner. In fact, the references in their entirety, taken alone or in combination, fail to provide the requisite teaching or suggestion to make the combination as proposed by the Examiner.

15. As held by the Federal Circuit in *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002), specific reasons must be shown in the art suggesting a combination of references. (See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (“[P]articular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.”); Also see, *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) (“[E]ven when the level

of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination.”)).

16. Applicants respectfully submit that the Examiner has failed to meet the above burden in the Section 103 rejection of claims 1, 24 and 29. Specifically, the provided motivation to combine the references is not supported by the art of record and, therefore, is based on impermissible hindsight. Specifically, the noted motivation provided by the Examiner is entirely insufficient to explain why one would modify the tip of Kuzma with a conical tapered portion tapering and extending distally from the distal end of the electrode array. (*See*, Office Action, page 6.)

17. Kuzma discloses an implantable electrode array adapted to be inserted into the cochlea, and which assumes a shape to hug the modiolar wall of the cochlea after insertion. A naturally curved positioning stylet made of shape-memory metal is cooled into a straight shape and inserted into the electrode array. As the stylet warms to body temperature, it returns to its spiral memory shape, causing the electrode array to also assume a spiral shape, thus positioning the electrode contacts against the modiolar wall. (*See*, Kuzma, Abstract.) FIG. 4 of Kuzma shows an electrode array which was formerly straight (shown as broken lines) but is now in a curved configuration. Kuzma further states that “soft tip 37, having a depth of distance L8, is typically formed from LSR-25 at the very distal tip of the electrode array 30. In the preferred embodiment, L8 has a value of approximately 0.3 mm.” (*See*, Kuzma, col. 11, ll. 39-42.)

18. Wappler describes a system for healing morbid organs by exposing the organ tissue to “nitrous oxid, ozonous and kindred gases” that are formed in a chamber. (*See*, Wappler, pg. 1, ll. 78-83.) Wappler describes prior systems utilizing glass electrodes which were liable to break during or after insertion into a human body. (*See*, Wappler, pg. 1, ll. 15-23.) In the Wappler invention, a tube 10 was surrounded by perforated metallic sheath conductor 14, thereby preventing the glass tube portion from bending when inserted into a human body. (*See*, Wappler, pg. 1, ll. 45-58.)

19. Since the electrode and tip of Wappler is prevented from bending due to Wappler’s metallic sheath, there is absolutely no reason why one of ordinary skill in the art would be

motivated to add the metallic sheath of Wappler to the electrode array of Kuzma. Doing so would have defeated the purpose of Kuzma, which describes an electrode array configured to be inserted into the cochlea – a process which requires the electrode array to bend during insertion.

20. For at least this reason, Applicants assert that the Examiner has failed to provide any indication as to why one of ordinary skill in the art would be motivated to combine Wappler with Kuzma as asserted by the Examiner. Therefore, Applicants assert that the motivation to combine the references cannot be found in the art of record, the rejection under Section 103 is based on impermissible hindsight, and should be withdrawn.

Proposed Combination of Wappler and Kuzma Fails to Teach or Suggest All Elements of Claims 1, 24 and 29

21. Further, even if Wappler were to be combined with Kuzma as suggested in the Office Action, the resulting device would still not result in, neither would it have the advantages of, the present invention without substantial modifications being made to the resulting system. As set forth in the MPEP at §2142, “to establish a *prima facie* case of obviousness... the prior art reference (or references when combined) must teach or suggest all of the claim limitations.”

22. As acknowledged by the Examiner, “Kuzma fails to teach a conical tapered portion tapering and extending distally from the distal end of the electrode array” as recited in Applicants’ claims 1, 24 and 29. (*See*, Office Action, pg. 5, ¶ 18.) However, the Examiner is mistaken in taking the position that the combination of Wappler and Kuzma teaches these elements. (*See*, Office Action, pages 4-5.)

23. As amended, independent claims 1, 24 and 29 recite “a ***flexible conical tapered portion tapering*** and extending distally from a distal end of said elongate carrier member, wherein said tip member is configured such that said tip member prevents substantial foldover of said tip when a deflection/impact force is applied to said tip member during implantation into the cochlea.” (*See*, Applicants’ independent claims 1, 24 and 29, as amended, above; emphasis added.)

24. As noted previously, Wappler describes a system for healing morbid organs by exposing the organ tissue to “nitrous oxid, ozonous and kindred gases” that are formed in a chamber. (*See*,

Wappler, pg. 1, ll. 78-83.) Wappler describes prior systems utilizing glass electrodes which were liable to break during or after insertion into a human body. (*See*, Wappler, pg. 1, ll. 15-23.) In the Wappler invention, a tube 10 was surrounded by perforated metallic sheath conductor 14. (*See*, Wappler, pg. 1, ll. 45-58.) Disposed within the length of tube 10 is a conductive coating 12 made of tinfoil. Coating 12 made contact with a metal cap 13, to which electricity was applied. Surrounding metallic sheath 14 around glass tube 10 forms an air chamber 17 between metallic sheath 14 and tube 10. When electricity is applied to metal cap 13, the electricity is said to flow via coating 12 through dielectric body 10 to ionize the air in the chamber 17 to form nitrous oxid[e], ozonous and kindred gases are formed that pass through the perforated metallic sheath conductor 14 to provide healing to the morbid organs. (*See*, Wappler, pg. 1, ll. 45-83.)

25. Therefore, assuming arguendo that proper motivation existed to combine the references as proposed, the combination of Kuzma and Wappler would result in a device having a metallic sheath surrounding the electrode array of Kuzma, where the resulting electrode array and tip would be inflexible when inserted into the recipient, rather than being a “***flexible conical tapered portion tapering*** and extending distally from a distal end of said elongate carrier member” as recited in Applicants’ claims 1, 24 and 29. Therefore, for at least the reason that neither Wappler or Kuzma teach all elements of Applicants’ claims 1, 24 and 29, including “a flexible conical tapered portion tapering and extending distally from a distal end of said elongate carrier member,” the Section 103 rejections of these claims are improper. Accordingly, Applicants respectfully request that these rejections be reconsidered and that they be withdrawn.

26. Independent claim 59 also recites a “tip member comprising a flexible conical tapered portion extending distally from a distal end of said elongate carrier member”, as recited in independent claims 1, 24 and 29. Therefore, Kuzma alone fails to teach or suggest all features of independent claim 59 and is allowable over the §103 rejection for reasons similar to those above for claims 1, 24 and 29. Accordingly, Applicants respectfully request that this rejection be reconsidered and that it be withdrawn.

Dependent claims

27. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

Conclusion

28. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

29. Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and Applicant reserves the right to pursue such claims in a continuation or divisional application.

Respectfully submitted,

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